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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,460	04/22/2004	Michael Ioelovich	P-6768-US	6428
27130	7590	11/30/2005	EXAMINER	
EITAN, PEARL, LATZER & COHEN ZEDEK LLP 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020			WHITE, EVERETT NMN	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 11/30/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,460

Applicant(s)

IOELOVICH ET AL.

Examiner

Everett White

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-25 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 27, 2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

1. Claims 1 and 18 are objected to because of the following informalities: In Claim 1, step (d), the phrase "homogenizing of the composition" should be changed to - - homogenizing the composition - -; In Claim 18, line 2, the phrase "that a about" should be changed to - - that about - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-6, 8, 9, 14, 15, and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 4, the metes and bounds of the derivatives of polyalkylenoxide polysiloxane cannot be determined since the name, structural formula or detail description of these derivatives have not been defined in the claims and the specification, which renders Claim 4 indefinite.

In Claims 5, 6, 8, 9, and 18-21, the bases of the weight percent has not been set in the claims which renders the claims indefinite. For example, in Claim 5, is the concentration of the non-ionic wetting agent based on the combined weight of cellulose, acidic catalyst and additive present in the hydrolyzing medium of step (a) of Claim 1 or based on some other material?

In Claim 15, the term "low-soluble precipitators" lacks clear antecedent basis because this term has not previously been set forth in claims from which it is dependent from, which renders the claim indefinite.

In Claims 22-24, line 1 of each claim, the term "comprising" should be changed to - - comprises - -. The currently used term make the claims incomplete.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by McGinley et al (US Patent No. 5,462,761).

Applicants claim a microcrystalline cellulose product characterized by uniformly dispersed micro-particle cellulose in the form of product-by-process claim. The Office considers product-by-process claims as product claims.

The McGinley et al patent discloses a composition comprising dry, water-dispersible particles of microcrystalline cellulose. See Example 9 (at column 7, lines 9-11) wherein the final mixture containing the microcrystalline composition is homogenized prior to drying, which anticipates the instantly claimed microcrystalline cellulose product characterized by uniformly dispersed micro-particle cellulose.

6. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Schaible et al (Pub. No. US 2003/0089465).

Applicants claim a microcrystalline cellulose product characterized by uniformly dispersed micro-particle cellulose in the form of product-by-process claim. The Office considers product-by-process claims as product claims.

The Schaible et al publication discloses microcrystalline cellulose (MCC) product in Examples 5 (see paragraphs 0185 to 0189), which anticipates the instantly claimed microcrystalline cellulose product of Claim 25 since Schaible et al publication discloses a MCC which is homogenized (see page 7, paragraph 0188, lines 4 and 5) which is characteristic of a MCC having uniformly dispersed micro-particles cellulose.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-3, 7-9, 12-14, 16-19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaible et al (Pub. No. US 2003/0089465) in view of McGinley et al (US Patent No. 5,462,761).

Applicants claim a method for the production of fractionally homogeneous compositions containing microcrystalline cellulose (MCC), comprising the steps: (a) hydrolyzing cellulose-containing raw material with a catalytic system comprising at least one acidic catalyst in the presence of at least one process additive at about

0.1 to 10 catalytic system/cellulose weight ratio; (b) neutralizing said acid with one or more precipitator in the manner that fine particles of insoluble ingredients precipitate into a slurry containing MCC; (c) admixing at least one modifier; and (d) homogenizing of the composition so that a MCC product characterized by a uniformly dispersed micro-particle cellulose material and various functional ingredients is obtained. Additional limitations in the dependent claims include the use of specific process additives; the use of specific precipitators; the use of specific modifiers; and additionally spray-drying micro-particle cellulose materials.

The Schaible et al publication discloses a process for preparing a pharmaceutical grade microcrystalline cellulose which comprises: hydrolyzing the cellulose at the time of cooking the pulp in the reactor (see the abstract). Additional steps set forth on page 2, paragraph 0022 of the Schaible et al publication that may be used to prepare the pharmaceutical grade microcrystalline cellulose product includes neutralizing a solution of the hydrolyzed cellulose and water to obtain a neutralized solution having a pH of at least 5.5, and preferably between 5.5 and 7.5; applying a shear force to deaggregate the hydrolyzed cellulose particles and provide a more uniform hydrolyzed cellulose material; and spray drying the hydrolyzed cellulose. See paragraph 0051 of the Schaible et al publication wherein organic acids such as acetic acid serve as catalysts for the hydrolysis of the cellulose. See paragraph 0069 of the Schaible et al publication wherein the repulping of the cellulose in water may be carried out in the presence of an additive. See paragraph 0082-0085 of the Schaible et al publication wherein hydrogen peroxide, magnesium sulphate and sodium hydroxide may be used in the process thereof which embraces the use of the additives and precipitators set forth in the instant claims.

The instantly claimed method for the production of compositions comprising microcrystalline cellulose differs from the process for producing microcrystalline cellulose of the Schiabile et al publication by claiming the use of a catalytic system comprising at least one acidic catalyst in the presence of at lease one process additive at about 0.1 to 10 catalytic system/cellulose weight ratio. However, on page 2, 3rd paragraph of the instant specification, Applicants suggest that it is known in the art to

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manufacture microcrystalline cellulose using a hydrolysis step comprising solutions of strong mineral acids and different acid/cellulose ratios ranging from 10 to 20. The acid/cellulose ratio of 10 overlaps the catalytic system/cellulose weight ratio disclosed in instant Claim 1.

The instantly claimed method for the production of compositions comprising microcrystalline cellulose also differs from the process for producing microcrystalline cellulose of the Schaible et al publication by claiming a step that involve admixing specific modifiers in the composition which was not noted in the Schaible et al publication. However, the McGinley et al patent, which discloses microcrystalline cellulose and glucomannan aggregates, shows that the presence of such modifiers in compositions comprising microcrystalline cellulose is well known in the art. See column 7, lines 22 and 23 wherein a fat/emulsifier blend is added to a MCC/konjac slurry and mixed.

One of ordinary skill in this art would be motivated to combine the teachings of the Schaible et al publication with the teachings of the McGinley et al patent to reject the claims under 35 U.S.C. 103 since both references disclose high grade microcrystalline cellulose products.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the process for producing microcrystalline cellulose of the Schaible et al publication a modifier such as fat/emulsifier blend in view of the recognition in the art, as evidenced by McGinley et al patent, that use of fat/emulsifier blend is a component of the composition thereof that increases the effectiveness of compositions as bulking agents and fat substitutes.

Claim Objections

9. Claims 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Summary

10. Claims 1-9, 12-25 are rejected; Claims 10 and 11 are objected to.

Examiner's Telephone Number, Fax Number, and Other Information

11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



E. White



Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600